UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,689	11/10/2003	Allan R. Dunn	1.275.03	4644

4219 7590 11/27/2007

MALLOY & MALLOY
2800 S.W. THIRD AVENUE
HISTORIC CORAL WAY
MIAMI, FL 33129

EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
11/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/705,689	DUNN, ALLAN R.	
	Examiner	Art Unit	
	Fozia M. Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,9-11,13-19 and 21-24* is/are pending in the application.

4a) Of the above claim(s) *1-3,5-7,9-11 and 13-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1a. Receipt of Applicants' amendment and arguments, filed on 27 August 2007 is acknowledged.

Status of Claims:

1b. Claims 4, 8, 12, 20 have been cancelled. New claims 21-24 have been added. Thus claims 1-3, 5-7, 9-11, 13-19 and 21-24 are pending, of which claims 1-3, 5-7, 9-11, 13-19 stand withdrawn as they are drawn to non-elected invention. Applicant has cancelled all the examined claims (4, 8, 12, 20) and added new claims 21-24, which are drawn to the same invention as the cancelled claims. Thus, claims 21-24 are under consideration.

Response to Applicants' arguments:

2. The following previous objections and rejections are withdrawn in light of Applicants' amendment and arguments files on 08/27/2007.

2a. All of the rejections of cancelled claims 4, 8, 12 and 20 are moot.

Applicant's Declaration:

3. The declaration submitted by the inventor Dr. Allan R. Dunn on 27 August 2007 has been considered, but is not deemed sufficient to render claims 21-24 patentable.

Applicant submits that he has conducted extensive research on the effects of low dosages of purified growth hormone from 1999 to 2007. Applicant states that a single intra-articular injection of purified growth hormone at dosages and concentrations of 0.025 to 0.249 milligrams of purified growth hormone per kilogram of body weight

dosages, administered at concentrations of about 5.0 to 6.0 milligrams per milliliter of buffer solution was effective in reducing and/or eliminating signs of inflammation, including pain, swelling, heat, and stiffness in the patients treated. Applicant further maintains that patients that received this lower dosage did not suffer from side effects, (such as elevated levels of glucose and headaches), that were associated with higher dosages of 0.25 to 0.75 milligrams per kilogram. Applicant argues that a composition comprising purified growth hormone at reduced dosages in the ranges recited in the claims, is significantly more economical than a composition comprising larger dosages of the purified growth hormone.

This is considered, but is not found persuasive. Applicant's results, that the lower dosage of purified growth hormone was effective in reducing and/or eliminating signs of inflammation, including pain, swelling, heat, and stiffness in the patients treated, with no side effects, is not disputed. However, growth hormone has been purified, expressed and been in use since 1974, (see below). Applicant has identified a new use of an old composition, thus, while a method of treatment using the lower dosages recited in the claims would be allowable, a composition comprising said lower dosages is not patentable, because growth hormone has been in the prior art domain since 1974.

New Rejections:

Claim rejections-35 USC § 102:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al, (3,853,833, issued 10 December 1974).

The instant claims 21-24 are drawn to a composition comprising a purified growth hormone dissolved in a buffer solution in specific concentrations.

Li et al disclose the purification and expression of human growth hormone, (figure 1, claims).

Therefore, Li et al reference anticipates instant claims 21-24, because the reference discloses the expression and purification of growth hormone. New formulations of an old product does not make it patentable. See MPEP §2112[r-3], which states:

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

In the instant case, the fact that Applicant discovered that 0.025 to 0.249 milligrams per kilogram of body weight dosage of Growth Hormone, was effective for reducing and/or eliminating signs of inflammation, including pain, swelling, heat, and stiffness in the patients treated, without any side effects does not make a composition comprising growth hormone patentable, because growth hormone has been in use, and thus in the prior art domain since 1974. Accordingly, while a method of treatment using

the lower dosages recited in the claims would be allowable, a composition comprising said lower dosages is not patentable, because growth hormone has been in the prior art domain since 1974.

Conclusion

5. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M. Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday-Friday: 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Fozia hamud
Patent Examiner
Art Unit 1647
20 November 2007

/Fozia M Hamud/

Examiner, Art Unit 1647